

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**MEFENAMIC ACID CAPSULES 250 mg**  
 Mefenamic acid

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

1. What Mefenamic Acid Capsules 250mg are and what they are used for
2. What you need to know before you take Mefenamic Acid Capsules 250mg
3. How to take Mefenamic Acid Capsules 250mg
4. Possible side effects
5. How to store Mefenamic Acid Capsules 250mg
6. Contents of the pack and other information

**1. What Mefenamic Acid Capsules 250mg are and what they are used for**

Mefenamic acid is one of the group of medicines called non-steroidal anti-inflammatory drugs. Mefenamic acid can relieve the pain and discomfort caused by: arthritis, headache, toothache, periods, fever in children, and may also be used after operations and childbirth.

**2. What you need to know before you take Mefenamic Acid Capsules 250mg**

**Do not take if you have, or have ever had, severe gastritis, a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation.**

**Do not take Mefenamic Acid Capsules if you:**

- Have a history of stomach bleeding or perforation which may be related to the use of NSAIDs (naproxen, ibuprofen, diclofenac) or aspirin
- Are allergic to mefenamic acid or any other ingredients of this medicine (listed in section 6)
- Have a history of allergy to aspirin, ibuprofen or NSAIDs, which includes attacks of asthma, swelling of the nose and throat, skin rashes or a runny nose
- Have a history of, or active disorders of the stomach or intestines such as ulcerative colitis, Crohn's disease, gastrointestinal cancers or diverticulitis (inflamed or infected pouches/pockets in the colon)
- Have severe heart failure
- Have severe liver or kidney failure
- Are in the last three months of your pregnancy
- Have recently had coronary artery bypass graft surgery.

If any of the above applies to you, **tell your doctor immediately and do not take Mefenamic Acid Capsules 250mg.**

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Mefenamic Acid Capsules if you:

- Suffer from asthma or have had a history of asthma, as this medicine may cause breathing difficulties
- Are an older person. Your doctor may prescribe another medicine to protect your stomach and intestines from side effects particularly if you are over 70 years old or are taking other medication
- Have ulcerative colitis or Crohn's disease
- Have systemic lupus erythematosus (SLE) which causes inflammation in various parts of the body or mixed connective tissue disorders (MCTD) as there may be an increased risk of aseptic meningitis (an illness characterised by headache, fever and inflammation of the lining of the brain)
- Are known to be a poor metaboliser of CYP2C9
- Suffer from kidney disease and dehydration (thirsty with dry skin, dark urine, dry mouth, headache)
- Suffer from liver disease
- Have diabetes
- Have heart problems, previous stroke or think you might be at risk of these conditions (For example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist
- Regularly take a painkiller for headaches over a prolonged period as it can make them worse
- Have a bleeding disorder or if you are going to have a major operation. Mefenamic Acid Capsules can affect the clotting of your blood. It can make you bleed more and for longer than usual
- Have epilepsy
- Are taking any other NSAIDs (e.g. ibuprofen, diclofenac)
- Are taking any other anti-inflammatory medicines including steroids (e.g. prednisolone)
- Are taking aspirin or medicines that thin the blood (e.g. warfarin, clopidogrel)
- Are taking antidepressants called selective serotonin re-uptake inhibitors (SSRIs) (e.g. paroxetine)
- Have a problem with the metabolism of sugar in your body.

Mefenamic acid may interfere with platelet function, therefore you should inform your doctor if you suffer from intracranial bleeding.

Medicines such as mefenamic acid may be associated with a small risk of heart attack ('myocardial infarction') or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

Mefenamic Acid Capsules may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

If you go into hospital or to see a doctor or dentist, tell them you are taking Mefenamic Acid Capsules.

**Other medicines and Mefenamic Acid Capsules 250mg**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

**The following medicines must not be taken with Mefenamic Acid Capsules:**

- Aspirin or other non-steroidal anti-inflammatory drugs for pain relief e.g. naproxen, diclofenac
- Anticoagulants such as warfarin to prevent blood clots.

Tell your doctor **before** you take Mefenamic Acid Capsules if you are taking any of the following medicines:

- Low dose aspirin (75mg) to help prevent heart attack or stroke
- Corticosteroids, which are drugs given to treat a variety of conditions such as allergies and hormone imbalances
- Certain medicines used to treat heart conditions known as cardiac glycosides such as digoxin
- Certain medicines for depression such as lithium or selective serotonin re-uptake inhibitors (SSRIs) e.g. fluoxetine, paroxetine, citalopram
- Antihypertensives and ACE inhibitors, used to treat high blood pressure
- Methotrexate which can be given to treat various conditions such as cancers, psoriasis and rheumatoid arthritis
- Cyclosporin, which is given to help prevent rejection of transplanted organs
- Quinolone antibiotics, which are used to treat various infections
- Mifepristone which is used to medically terminate pregnancies
- Diuretics such as hydrochlorothiazide to treat high blood pressure or kidney problems (water tablets)
- Anti-platelet agents (used to prevent blood clots from forming that can lead to heart attack or stroke) e.g. aspirin, clopidogrel, ticlopidine, dipyridamole
- Tacrolimus which is used to suppress the immune system after organ transplant
- Zidovudine which is used in the treatment of AIDS and HIV infection
- Aminoglycoside antibiotics, e.g. streptomycin
- Probenecid used in the treatment of gout
- Some diabetic medicines such as (e.g. glipizide, glibenclamide).

**Mefenamic Acid Capsules 250mg with food and drink**

Always take the capsules with plenty of water, preferably after a meal. Try to take them at the same time every day.

**Blood tests:**

Your doctor may test your blood during treatment.

**Pregnancy, breast-feeding and fertility**

**Pregnancy**

Mefenamic acid will be passed to your unborn baby. It is not known how much it will affect your unborn baby in the first 6 months of pregnancy. Do not take mefenamic acid capsules if you are in the last three months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take mefenamic acid capsules during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, mefenamic acid capsules can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

**Breast-feeding**

Mefenamic acid passes into breast milk and can affect the baby. You should not take the capsules while breast-feeding unless advised by your doctor.

**Fertility**

Do not take the capsules if you are trying to become pregnant, as they may make it more difficult to get pregnant.

You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

**Driving and using machines**

Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected, do not drive or operate machinery.

**Mefenamic Acid Capsules 250mg contain lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**Information on sodium content**

This medicine contains less than 1 mmol sodium (23 mg) per capsule, i.e. is essentially 'sodium-free'.

**3. How to take Mefenamic Acid Capsules 250mg**

Always take Mefenamic Acid Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The side effects may be minimised by using the lowest effective dose for the shortest duration necessary to control your symptoms. Your doctor may monitor you at frequent intervals.

210 x 340 mm

FRONT SIDE



**ARTWORK DETAIL LABEL**

<b>Product</b>	Mefenamic Acid Capsules - 250 mg		
Buyer/Country	SPUK	Component	Pack Insert
<b>Dimension</b>	210 x 340 mm - Same Size		Pack ----
<b>New Item Code</b>	1048081	Old Item Code	1047117
Colour Shades	BLACK	No. of Colours	1
Change Control No.	Record Number: 358955	Artwork Version	7.0
Design/Style	Front and Back printing, to be supplied in the folded booklet form with pasting and folded size: 29 x 29 mm.		
Substrate	40/45 GSM Paper.		
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.		
Autocartonator Requirements	NA		
<b>Caution to the printer:</b> Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. <b>DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.</b>			

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Swallow your capsules whole with a glass of water. It is best to take your capsules at the same time each day with food or soon after eating.

**Adults:**

The recommended dose is 2 capsules (500mg) taken 3 times a day. However your doctor may suggest a different dose.

**Older people:** Your doctor may prescribe a lower dose.

If you are older than 70 years your doctor may prescribe a lower daily dose and reduce the duration of treatment.

If you are older than 80 years you may be given other medication to protect your stomach such as misoprostol.

**Use in children and adolescents:**

This medicine is not recommended for children under 12 years of age.

**If you take more Mefenamic Acid Capsules 250mg than you should**

If you accidentally take too many Mefenamic Acid Capsules, tell your doctor at once. If you can't do this, go to the nearest hospital casualty department. Symptoms may include headaches, feeling sick, vomiting, stomach pain, diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, ringing in ears, fainting and occasionally convulsions. Take along any capsules that are left, the container and the label so that the hospital staff can easily tell what medicine you have taken.

Do this even if you feel well.

**If you forget to take Mefenamic Acid Capsules 250mg**

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Mefenamic Acid Capsules 250mg**

Continue to take the capsules for as long as your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible Side Effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you suffer from any of the following at any time during your treatment

**STOP TAKING** the medicine and seek immediate medical attention.

- Pass blood in you faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds
- Severe itching of the skin, with a red rash or raised lumps (hives).

**STOP TAKING** the medicine and tell your doctor if you experience:

- Indigestion or heartburn
- Abdominal pain (pains in your stomach) or other abnormal stomach symptoms
- Sudden wheeziness, difficulty in breathing, fever, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body) (anaphylaxis)
- A rash, blistering or peeling of the skin, mouth, eyes or genitals (toxic epidermal necrolysis)
- Yellowing of the skin and the whites of your eyes (jaundice) which may be a sign of hepatitis or other liver problems
- Severe spreading skin rash (Stevens-Johnson Syndrome and erythema multiforme, symptoms include severe skin rash, blistering of skin, including inside mouth, nose and genitals, as well as skin peeling which may be accompanied with symptoms such as aching, headaches and feverishness).

The most commonly reported side effects with Mefenamic Acid Capsules are gastrointestinal in nature and effect the stomach and intestines.

These are:

- Diarrhoea or constipation, wind
- Feeling sick (nausea), vomiting, loss of appetite
- Sore mouth and/or lips
- Stomach ache, indigestion, abdominal pain/discomfort
- Stomach (peptic) ulcers
- Holes or bleeding in the digestive tract
- Blood in the stools or urine
- Oily stools
- Worsening of inflammation of the digestive tract
- Inflammation of the pancreas, stomach, small intestine or colon
- Lack or loss of appetite for food.

Other side effects that have been reported include:

**Effects on your heart and circulation:**

- Medicines such as mefenamic acid may be associated with a small increased risk of heart attack (myocardial infarction) or stroke
- Fast or pounding heartbeat
- High blood pressure
- Swollen ankles and/or feet (oedema)
- Low blood pressure
- Heart failure.

**Effects on the stomach and intestines:**

- Stomach ulcers, holes or bleeding in the digestive tract, feeling sick (nausea), vomiting, wind, constipation, indigestion, tummy pain, blood in the stools or urine, oily stools, mouth ulcers, worsening of inflammation of the digestive tract, inflammation of the pancreas or stomach
- Diarrhoea
- Passage of black, tarry stools with a strong distinctive odour
- Vomiting of blood
- Anorexia
- Inflammation of both the small intestine and the colon.

**Effects on your nervous system:**

- Dizziness
- Vertigo (a spinning sensation)
- Headache, changes in sleep patterns, abnormal dreams, insomnia

- Depression, nervousness, hallucinations, mood alterations, mental confusion
- Pins and needles
- There are reports of aseptic meningitis (especially with patients with existing autoimmune disorders such as systemic lupus erythematosus SLE) with symptoms of stiff neck, headache, nausea, vomiting and fever
- Convulsions
- Drowsiness
- Eye pain
- Disorientation and blurred vision.

**Effects on your skin:**

- Rashes, itching, redness, tenderness, thickening or scaling of skin
- Increased sensitivity of the skin to sunlight
- Discolouring of the skin, perspiration
- Red or purple discoloured spots on the skin
- Swelling of the skin
- Blistering of the skin.

**Effects on your kidneys:**

- Kidney inflammation, kidney failure or kidney damage including renal papillary necrosis. If you notice any change in your urine output or appearance, possibly accompanied by kidney pain, or pain in your abdomen or back **contact your doctor**
- Painful urination.

**Effects on your liver:**

- Jaundice and hepatitis (inflammation of the liver) mild hepatotoxicity. If you notice a yellowing of your skin or eyes **contact your doctor**
- Liver problems and abnormal liver function tests.

**Effects on blood and medical tests:**

- Changes in the numbers of red and white blood cells (these can be detected by your doctor who will stop your treatment) in blood and other biochemical tests. These effects may result in unusual bruising or bleeding (for example nose-bleeds, pinpoint red spots on the skin, unusual purple bruise-like rash on the skin or in the mouth) or increased risk of infection
- Changes in blood sugar levels may also occur
- Severe infection which results in blood poisoning (sepsis).

**Effects on your eyes and ears:**

- Hearing impairment, ringing in ears, vertigo, ear pain
- Swollen eyes, blurred vision, eye irritation, reversible loss of colour vision.

**Effects on your metabolism:**

- Inability to control glucose levels in diabetics
- Reduced sodium levels measured by a blood test.

**General**

- Increased body temperature, multi-organ failure
- Feeling unwell
- Tiredness.

**Effects on your breathing:**

- Asthma or asthma that is worse than usual or shortness of breath.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Mefenamic Acid Capsules 250mg**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not use this medicine if you notice visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

**6. Contents of the pack and other information**

**What Mefenamic Acid Capsules contain**

The active substance is Mefenamic Acid BP/Ph.Eur. The other ingredients are lactose monohydrate, gelatin, sodium starch glycollate, sodium laurilsulfate, patent blue V (E131), erythrosine (E127), titanium dioxide (E171), yellow iron oxide (E172), shellac, black iron oxide (E172), soya lecithin and dimeticone.

**What Mefenamic Acid Capsules look like and contents of the pack:**

Description: Off white granule in a size 1 capsule shell with a blue cap and buff body, printed with MEF 250 both on body and cap.

**Contents of pack:**

HDPE white opaque round plastic container with HDPE white opaque screw cap.

Available in pack sizes: 50, 84, 100, 250, 500 and 1000 capsules.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

**Strides Pharma UK Ltd.**  
Unit 4, The Metro Centre, Dwight Road,  
Watford, WD18 9SS, United Kingdom  
Tel: 01923 255580  
Fax: 01923 255581

**This leaflet was last revised in November 2022.**



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1048081




10234

210 x 340 mm

BACK SIDE

**ARTWORK DETAIL LABEL**

<b>Product</b>	<b>Mefenamic Acid Capsules - 250 mg</b>		
Buyer/Country	SPUK	Component	Pack Insert
<b>Dimension</b>	210 x 340 mm - Same Size		Pack ----
<b>New Item Code</b>	<b>1048081</b>	Old Item Code	1047117
Colour Shades	 BLACK	No. of Colours	1
Change Control No.	Record Number: 358955		Artwork Version 7.0
Design/Style	Front and Back printing, to be supplied in the folded booklet form with pasting and folded size: 29 x 29 mm.		
Substrate	40/45 GSM Paper.		
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.		
Autocartonator Requirements	NA		
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